MAY 10 2012

K120537
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510(k) Summary

Submitter:	Medtronic Advanced Energy 180 International Drive Portsmouth, NH 03801
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Date Prepared:	February 17th, 2012
Trade Name:	Aquamantys3 9.5 XL Bipolar Sealer
Common Name:	Electrosurgical Bipolar Sealer
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Predicate Device:	Disposable Device Predicate: K101057, cleared April 5th, 2011 Cassette Predicate: K111285, cleared September 9th, 2011
Device Description:	The Aquamantys3 9.5 XL Bipolar sealer represents a line extension to the predicate Aquamantys 9.5 XL Bipolar Sealer (cleared as the Double Cone Bipolar Sealer in K101057) and the Aquamantys product family. Similar to the predicate devices, it is a sterile, single-use hemostatic sealing device. The device employs bipolar radio-frequency (RF) energy and saline for blunt dissection and for hemostatic sealing and coagulation. The device is equipped with a dual electrode tip with saline apertures at its distal end. Saline and RF energy are supplied to the device from lines on the proximal end of the handpiece and connection to the Aquamantys3 Pump Generator via the distally attached cassette interface.
Statement of Intended Use:	The Aquamantys3 9.5 XL Bipolar Sealer is a single use, sterile, bipolar device intended to be used in conjunction with the Aquamantys3 Pump Generator for delivery of radio-frequency (RF) energy and saline for blunt dissection and for haemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to, open

	abdominal, orthopaedic, and thoracic surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).
Summary of Technological Characteristics:	The modified single-use disposable accessory device, the Aquamantys3 9.5 XL Bipolar Sealer, is similar to the Aquamantys 9.5 XL Bipolar Sealer such that both devices provide concurrent delivery of bipolar RF energy with saline. The two devices share identical handpiece, shaft and tip configurations and differ only in how they connect to their respective, designated generators. The cord of the predicate Aquamantys 9.5 XL Bipolar Sealer terminates in a standard three-prong electrical connector and has saline tubing that is manually loaded as an additional step into the peristaltic pump. The cord of the proposed Aquamantys3 9.5 XL Bipolar Sealer terminates in a cassette that is designed to uniquely insert into the Aquamantys3 Pump Generator, providing simultaneous connection to both RF power and the peristaltic pump. This cassette interface is part of the predicate Aquamantys3 6.0 Bipolar Sealer device.
Summary of Non-clinical Data:	The Aquamantys3 9.5 XL Bipolar Sealer has undergone bench performance testing to verify and validate the performance features and specifications. The testing included: • static cable pulls, • dynamic cord pulls, • static saline tube pulls, • air leak and flow, • hipot testing, • saline flow testing, • continuity • biocompatibility assessment. All testing met the acceptance criteria.
Summary of Clinical Data:	Clinical testing was not required to establish substantial equivalence between the proposed and predicate devices.
Conclusion from Data:	Medtronic Advanced Energy has demonstrated that the Aquamantys3 9.5 XL Bipolar Sealer is substantially equivalent to the predicate device based upon indications for use, design, test results and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic, Inc.
% Tara N. Turney
180 International Drive
Portsmouth, NH 03801

MAY 10 2012

Re: K120537
Trade Name: Aquamantys3 9.5 XL Bipolar Sealer
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 25, 2012
Received: April 26, 2012

Dear Ms. Turney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. We remind you, however, that device labeling must be truthful and not misleading.

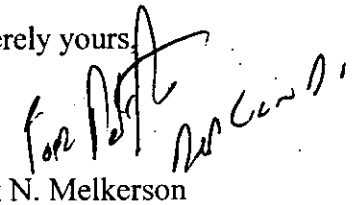
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120537

Device Name: Aquamantys3 9.5 XL Bipolar Sealer

Indications for Use: The Aquamantys3 9.5 XL Bipolar Sealer is a single use, sterile, bipolar device intended to be used in conjunction with the Aquamantys3 Pump Generator for delivery of radio-frequency (RF) energy and saline for blunt dissection and for haemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to, open abdominal, orthopaedic, and thoracic surgery.
The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120537
